

WHAT IS CLAIMED IS:

1 A method for inhibiting the action of TNF for treating neurological conditions in a human by administering a TNF antagonist for reducing the inflammation of neuronal tissue or the neuromuscular junction of said human, or for modulating the immune response affecting neuronal tissue or the neuromuscular junction of said human, comprising the step of:

a) administering a therapeutically effective dosage level to said human of said TNF antagonist selected from the group consisting of etanercept, infliximab, pegylated soluble TNF receptor Type I (PEGsTNF-R1), other agents containing soluble TNF receptors, CDP571 (a humanized monoclonal anti-TNF-alpha antibody), other monoclonal anti-TNF-alpha antibodies, TNF - alpha converting enzyme inhibitors and D2E7 (a human anti-TNF mAb) for reducing the inflammation of neuronal tissue or the neuromuscular junction of said human, or for modulating the immune response affecting neuronal tissue or the neuromuscular junction of said human.

2. A method for inhibiting the action of TNF in accordance with Claim 1, wherein the step of administering said TNF antagonist is performed through any of the following routes: subcutaneous, intravenous, intrathecal, intramuscular, intranasal, oral, transepidermal, parenteral, by inhalation, or intracerebroventricular.

3. A method for inhibiting the action of TNF in accordance with Claim 1, wherein the step of administering said dosage level is for treating neurodegenerative diseases including Alzheimer's disease, Huntington's disease and Creutzfeld-Jakob disease.

5 4. A method for inhibiting the action of TNF in accordance with Claim 1, wherein the step of administering said dosage level is for treating Parkinson's disease.

10 5. A method for inhibiting the action of TNF in accordance with Claim 1, wherein the step of administering said dosage level is for treating myasthenia gravis.

15 6. A method for inhibiting the action of TNF in accordance with Claim 1, wherein the step of administering said dosage level is for treating Guillain-Barre syndrome.

7. A method for inhibiting the action of TNF in accordance with Claim 1, wherein the step of administering said dosage level is for treating Bell's palsy.

20 8. A method for inhibiting the action of TNF in accordance with Claim 1, wherein the step of administering said dosage level is for treating neurological traumas and injuries, and for treating <sup>neurological</sup> diseases and disorders.

9. A method for inhibiting the action of TNF in accordance with Claim 1,  
wherein the step of administering said dosage level is for treating acute spinal cord or  
brain injury.

5 10. A method for inhibiting the action of TNF in accordance with Claim 1,  
wherein the step of administering said dosage level is for treating primary or metastatic  
brain tumors.

10 11. A method for inhibiting the action of TNF in accordance with Claim 1,  
wherein the step of administering said dosage level is for treating chronic pain syndrome  
due to metastatic tumor.

15 12. A method for inhibiting the action of TNF in accordance with Claim 1,  
wherein the step of administering said dosage level is for treating peripheral neuropathies,  
including diabetic neuropathy.

20 13. A method for inhibiting the action of TNF in accordance with Claim 1,  
wherein the step of administering said dosage level is for treating central nervous system  
lesions.

14. A method for inhibiting the action of TNF in accordance with Claim 1, wherein the step of administering said dosage level is for treating autoimmune neurological diseases.

5 15. A method for inhibiting the action of TNF in accordance with Claim 1, wherein the step of administering said dosage level is for treating multiple sclerosis.

10 16. A method for inhibiting the action of TNF in accordance with Claim 1, wherein the step of administering said dosage level is for treating inflammatory CNS diseases including subacute sclerosing panencephalitis.

15 17. A method for inhibiting the action of TNF in accordance with Claim 1, wherein the step of administering said dosage level is for treating amyotrophic lateral sclerosis.

20 18. A method for inhibiting the action of TNF in accordance with Claim 1, wherein the step of administering said TNF antagonist is performed subcutaneously in said human wherein said dosage level is in the range of 5mg to 50mg for acute or chronic regimens.

19. A method for inhibiting the action of TNF in accordance with Claim 1, wherein the step of administering said TNF antagonist is performed intranasally in said human wherein said dosage level is in the range of 0.1mg to 10mg for acute or chronic regimens.

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20. A method for inhibiting the action of TNF in accordance with Claim 1, wherein the step of administering said TNF antagonist in the form of etanercept is performed intramuscularly in said human wherein said dosage level is in the range of 25mg to 100mg.

21. A method for inhibiting the action of TNF in accordance with Claim 1, wherein the step of administering said TNF antagonist in the form of infliximab is performed intravenously in said human wherein said dosage level is in the range of 2.5 mg/kg to 20mg/kg.

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22. A method for inhibiting the action of TNF in accordance with Claim 1, wherein the step of administering said TNF antagonist in the form of etanercept is performed subcutaneously in said human wherein said dosage level is in the range of 5mg to 50mg.

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23. A method for inhibiting the action of TNF in accordance with Claim 1, wherein the step of administering said TNF antagonist in the form of etanercept is performed intrathecally in said human wherein said dosage level is in the range of 0.1mg to 25mg administered from once a day to once every three months.

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24. A method for inhibiting the action of TNF in accordance with Claim 1, wherein the step of administering said TNF antagonist in the form of infliximab is performed intrathecally in said human wherein said dosage level is in the range of 0.1mg/kg to 5mg/kg administered from once a week to once every three months.

25. A method for inhibiting the action of TNF in accordance with Claim 1, wherein the step of administering said TNF antagonist is performed transepidermally in said human wherein said dosage level is in the range of 10mg to 100mg.

26. A method for inhibiting the action of TNF in accordance with Claim 1, wherein the step of administering said TNF antagonist is performed by inhaling in said human wherein said dosage level is in the range of 0.2mg to 40mg.

27. A method for inhibiting the action of TNF in accordance with Claim 1, wherein the step of administering said TNF antagonist is performed intravenously in said human wherein said dosage level is a therapeutically effective amount.

5 28. A method for inhibiting the action of TNF in accordance with Claim 1, wherein the step of administering said TNF antagonist in the form of etanercept is performed intracerebroventricularly in said human wherein said dosage level is in the range of 0.1mg to 25mg administered once a day to once a month.

10 29. A method for inhibiting the action of TNF in accordance with Claim 1, wherein the step of administering said TNF antagonist in the form of infliximab is performed intracerebroventricularly in said human wherein said dosage level is in the range of 0.1mg/kg to 5mg/kg administered once a week to once every 3 months.

15 30. A method for inhibiting the action of TNF for treating conditions of the optic nerve or retina in a human by administering a TNF antagonist for reducing the inflammation of the optic nerve or retina of said human, or for modulating the immune response affecting the optic nerve or retina of said human, comprising the step of:

a) administering a therapeutically effective dosage level to said human of said TNF antagonist selected from the group consisting of etanercept, infliximab, pegylated soluble TNF receptor Type I (PEGsTNF-R1), other agents containing soluble TNF receptors, CDP571 (a humanized monoclonal anti-TNF-alpha antibody), and other  
5 monoclonal anti-TNF-alpha antibodies, TNF - alpha converting enzyme inhibitors and D2E7 (a human anti-TNF mAb) for reducing the inflammation of the optic nerve or retina of said human, or for modulating the immune response affecting the optic nerve or retina of said human.

10 31. A method for inhibiting the action of TNF in accordance with Claim 30, wherein the step of administering said TNF antagonist is performed through any of the following routes: subcutaneous, intravenous, intrathecal, intramuscular, intranasal, oral, transepidermal, parenteral, by inhalation, or intracerebroventricular.

15 32. A method for inhibiting the action of TNF in accordance with Claim 30, wherein the step of administering said dosage level is for treating disorders of the optic nerve or retina.

20 33. A method for inhibiting the action of TNF in accordance with Claim 30, wherein the step of administering said dosage level is for treating optic neuritis.

34. A method for inhibiting the action of TNF in accordance with Claim 30,  
wherein the step of administering said dosage level is for treating macular degeneration.

35. A method for inhibiting the action of TNF in accordance with Claim 30,  
5 wherein the step of administering said dosage level is for treating retinitis pigmentosa.

36. A method for inhibiting the action of TNF in accordance with Claim 30,  
wherein the step of administering said dosage level is for treating diabetic retinopathy.

37. A method for inhibiting the action of TNF in accordance with Claim 30,  
wherein the step of administering said TNF antagonist is performed subcutaneously in  
said human wherein said dosage level is in the range of 5mg to 50mg for acute or chronic  
regimens.

15 38. A method for inhibiting the action of TNF in accordance with Claim 30,  
wherein the step of administering said TNF antagonist is performed intranasally in said  
human wherein said dosage level is in the range of 0.1mg to 10mg for acute or chronic  
regimens.

39. A method for inhibiting the action of TNF in accordance with Claim 30, wherein the step of administering said TNF antagonist in the form of etanercept is performed intramuscularly in said human wherein said dosage level is in the range of 25mg to 100mg.

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40. A method for inhibiting the action of TNF in accordance with Claim 30, wherein the step of administering said TNF antagonist in the form of infliximab is performed intravenously in said human wherein said dosage level is in the range of 2.5 mg/kg to 20mg/kg.

41. A method for inhibiting the action of TNF in accordance with Claim 30, wherein the step of administering said TNF antagonist in the form of etanercept is performed subcutaneously in said human wherein said dosage level is in the range of 5mg to 50mg.

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42. A method for inhibiting the action of TNF in accordance with Claim 30, wherein the step of administering said TNF antagonist in the form of etanercept is performed intrathecally in said human wherein said dosage level is in the range of 0.1mg to 25mg administered from once a day to once every three months.

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43. A method for inhibiting the action of TNF in accordance with Claim 30, wherein the step of administering said TNF antagonist in the form of infliximab is performed intrathecally in said human wherein said dosage level is in the range of 0.1mg/kg to 5mg/kg administered from once a week to once every three months.

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44. A method for inhibiting the action of TNF in accordance with Claim 30, wherein the step of administering said TNF antagonist is performed transepidermally in said human wherein said dosage level is in the range of 10mg to 100mg.

45. A method for inhibiting the action of TNF in accordance with Claim 30, wherein the step of administering said TNF antagonist is performed intravenously in said human wherein said dosage level is a therapeutically effective amount.

46. A method for inhibiting the action of TNF in accordance with Claim 30, wherein the step of administering said TNF antagonist is performed orally by said human wherein said dosage level is in the range of 10mg to 300mg.

47. A method for inhibiting the action of TNF in accordance with Claim 30, wherein the step of administering said TNF antagonist is performed by inhaling in said human wherein said dosage level is in the range of 0.2mg to 40mg.

5        48. A method for inhibiting the action of TNF in accordance with Claim 30, wherein the step of administering said TNF antagonist in the form of etanercept is performed intracerebroventricularly in said human wherein said dosage level is in the range of 0.1mg to 25mg administered once a day to once a month.

10       49. A method for inhibiting the action of TNF in accordance with Claim 30, wherein the step of administering said TNF antagonist in the form of infliximab is performed intracerebroventricularly in said human wherein said dosage level is in the range of 0.1mg/kg to 5mg/kg administered once a week to once every 3 months.

15       50. A method for inhibiting the action of TNF for treating muscular diseases in a human by administering a TNF antagonist for reducing the inflammation of muscle of said human, or for modulating the immune response affecting the muscle of said human, comprising the step of:

a) administering a therapeutically effective dosage level to said human of said TNF antagonist selected from the group consisting of etanercept, infliximab, pegylated soluble TNF receptor Type I (PEGsTNF-R1), and other agents containing soluble TNF receptors, CDP571 (a humanized monoclonal anti-TNF-alpha antibody),  
5 other monoclonal anti-TNF-alpha antibodies, TNF - alpha converting enzyme inhibitors and D2E7 (a human anti-TNF mAb) for reducing the inflammation of muscle of said human, or for modulating the immune response affecting the muscle of said human.

51. A method for inhibiting the action of TNF in accordance with Claim 50,  
10 wherein the step of administering said TNF antagonist is performed through any of the following routes: subcutaneous, intravenous, intrathecal, intramuscular, intranasal, oral, transepidermal, parenteral, by inhalation, or intracerebroventricular.

52. A method for inhibiting the action of TNF in accordance with Claim 50,  
15 wherein the step of administering said dosage level is for treating muscular dystrophy.

53. A method for inhibiting the action of TNF in accordance with Claim 50,  
wherein the step of administering said dosage level is for treating polymyositis-  
dermatomyositis.

54. A method for inhibiting the action of TNF in accordance with Claim 50, wherein the step of administering said TNF antagonist is performed subcutaneously in said human wherein said dosage level is in the range of 5mg to 50mg for acute or chronic regimens.

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55. A method for inhibiting the action of TNF in accordance with Claim 50, wherein the step of administering said TNF antagonist is performed intranasally in said human wherein said dosage level is in the range of 0.1mg to 10mg for acute or chronic regimens.

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56. A method for inhibiting the action of TNF in accordance with Claim 50, wherein the step of administering said TNF antagonist in the form of etanercept is performed intramuscularly in said human wherein said dosage level is in the range of 25mg to 100mg.

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57. A method for inhibiting the action of TNF in accordance with Claim 50, wherein the step of administering said TNF antagonist in the form of infliximab is performed intravenously in said human wherein said dosage level is in the range of 2.5 mg/kg to 20mg/kg.

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58. A method for inhibiting the action of TNF in accordance with Claim 50, wherein the step of administering said TNF antagonist in the form of etanercept is performed subcutaneously in said human wherein said dosage level is in the range of 5mg to 50mg.

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59. A method for inhibiting the action of TNF in accordance with Claim 50, wherein the step of administering said TNF antagonist in the form of etanercept is performed intrathecally in said human wherein said dosage level is in the range of 0.1mg to 25mg administered from once a day to once a month.

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60. A method for inhibiting the action of TNF in accordance with Claim 50, wherein the step of administering said TNF antagonist in the form of infliximab is performed intrathecally in said human wherein said dosage level is in the range of 0.1mg/kg to 5mg/kg administered from once a week to once every three months.

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61. A method for inhibiting the action of TNF in accordance with Claim 50, wherein the step of administering said TNF antagonist is performed transepidermally in said human wherein said dosage level is in the range of 10mg to 100mg.

62. A method for inhibiting the action of TNF in accordance with Claim 50, wherein the step of administering said TNF antagonist is performed by inhaling in said human wherein said dosage level is in the range of 0.2mg to 40mg.

5 63. A method for inhibiting the action of TNF in accordance with Claim 50, wherein the step of administering said TNF antagonist is performed intravenously in said human wherein said dosage level is a therapeutically effective amount.

64. A method for inhibiting the action of TNF in accordance with Claim 50, wherein the step of administering said TNF antagonist in the form of etanercept is performed intracerebroventricularly in said human wherein said dosage level is in the range of 0.1mg to 25mg administered once a day to once a month.

15 65. A method for inhibiting the action of TNF in accordance with Claim 50, wherein the step of administering said TNF antagonist in the form of infliximab is performed intracerebroventricularly in said human wherein said dosage level is in the range of 0.1mg/kg to 5mg/kg administered once a week to once every 3 months.

66. A method for inhibiting the action of TNF for treating neurological conditions in a human by administering a TNF antagonist for reducing the inflammation of neuronal tissue or the neuromuscular junction of said human, or for modulating the immune response affecting neuronal tissue or the neuromuscular junction of said human, comprising the step of:

a) administering a therapeutically effective dosage level to said human of said TNF antagonist selected from the group consisting of thalidomide, phosphodiesterase 4 (IV) inhibitor thalidomide analogues and other phosphodiesterase IV inhibitors for reducing the inflammation of neuronal tissue or the neuromuscular junction of said human, or for modulating the immune response affecting neuronal tissue or the neuromuscular junction of said human.

67. A method for inhibiting the action of TNF in accordance with Claim 66, wherein the step of administering said TNF antagonist is performed orally.

68. A method for inhibiting the action of TNF in accordance with Claim 66, wherein the step of administering said dosage level is for treating neurodegenerative diseases including Alzheimer's disease, Huntington's disease and Creutzfeld-Jakob disease.

69. A method for inhibiting the action of TNF in accordance with Claim 66,  
wherein the step of administering said dosage level is for treating Parkinson's disease.

70. A method for inhibiting the action of TNF in accordance with Claim 66,  
wherein the step of administering said dosage level is for treating myasthenia gravis.

71. A method for inhibiting the action TNF in accordance with Claim 66, wherein  
the step of administering said dosage level is for treating Guillain-Barre syndrome.

72. A method for inhibiting the action of TNF in accordance with Claim 66,  
wherein the step of administering said dosage level is for treating Bell's palsy.

73. A method for inhibiting the action of TNF in accordance with Claim 66,  
wherein the step of administering said dosage level is for treating neurological traumas  
and injuries, and for treating diseases and disorders.

74. A method for inhibiting the action of TNF in accordance with Claim 66,  
wherein the step of administering said dosage level is for treating acute spinal cord or  
brain injury.

75. A method for inhibiting the action of TNF in accordance with Claim 66,  
wherein the step of administering said dosage level is for treating primary or metastatic  
brain tumors.

5 76. A method for inhibiting the action of TNF in accordance with Claim 66,  
wherein the step of administering said dosage level is for treating chronic pain syndrome  
due to metastatic tumor.

10 77. A method for inhibiting the action of TNF in accordance with Claim 66,  
wherein the step of administering said dosage level is for treating central nervous system  
lesions.

15 78. A method for inhibiting the action of TNF in accordance with Claim 66,  
wherein the step of administering said dosage level is for treating autoimmune  
neurological diseases.

79. A method for inhibiting the action of TNF in accordance with Claim 66,  
wherein the step of administering said dosage level is for treating multiple sclerosis.

80. A method for inhibiting the action of TNF in accordance with Claim 66, wherein the step of administering said dosage level is for treating inflammatory CNS diseases including subacute sclerosing panencephalitis.

5 81. A method for inhibiting the action of TNF in accordance with Claim 66, wherein the step of administering said dosage level is for treating amyotrophic lateral sclerosis.

10 82. A method for inhibiting the action of TNF in accordance with Claim 66, wherein the step of administering said TNF antagonist in the form of said thalidomide group is performed orally in said human wherein said dosage level is in the range of 10mg to 300mg.

15 ~~83.~~ A method for inhibiting the action of TNF for treating conditions of the optic nerve or retina in a human by administering a TNF antagonist for reducing the inflammation of the optic nerve or retina of said human, or for modulating the immune response affecting the optic nerve or retina of said human, comprising the step of:

a) administering a therapeutically effective dosage level to said human of said TNF antagonist selected from the group consisting of thalidomide, phosphodiesterase 4 (IV) inhibitor thalidomide analogues and other phosphodiesterase IV inhibitors for reducing the inflammation of the optic nerve or retina of said human, or for  
5 modulating the immune response affecting the optic nerve or retina of said human.

84. A method for inhibiting the action of TNF in accordance with Claim 83, wherein the step of administering said TNF antagonist is performed orally.

85. A method for inhibiting the action of TNF in accordance with Claim 83, wherein the step of administering said dosage level is for treating disorders of the optic  
10 nerve or retina.

86. A method for inhibiting the action of TNF in accordance with Claim 83, wherein the step of administering said dosage level is for treating optic neuritis.  
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87. A method for inhibiting the action of TNF in accordance with Claim 83, wherein the step of administering said dosage level is for treating macular degeneration.

88. A method for inhibiting the action of TNF in accordance with Claim 83, wherein the step of administering said dosage level is for treating retinitis pigmentosa.  
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89. A method for inhibiting the action of TNF in accordance with Claim 83,  
wherein the step of administering said dosage level is for treating diabetic retinopathy.

90. A method for inhibiting the action of TNF in accordance with Claim 83,  
wherein the step of administering said TNF antagonist in the form of said thalidomide  
group is performed orally in said human wherein said dosage level is in the range of  
10mg to 300mg.

91. A method for inhibiting the action of TNF for treating muscular diseases in a  
human by administering a TNF antagonist for reducing the inflammation of muscle of  
said human, or for modulating the immune response affecting the muscle of said human,  
comprising the step of:

a) administering a therapeutically effective dosage level to said human  
of said TNF antagonist selected from the group consisting of thalidomide,  
phosphodiesterase 4 (IV) inhibitor thalidomide analogues and other phosphodiesterase IV  
inhibitors for reducing the inflammation of muscle of said human, or for modulating the  
immune response affecting the muscle of said human.

92. A method for inhibiting the action of TNF in accordance with Claim 91,  
wherein the step of administering said TNF antagonist is performed orally.

93. A method for inhibiting the action of TNF in accordance with Claim 91,  
wherein the step of administering said dosage level is for treating muscular dystrophy.

94. A method for inhibiting the action of TNF in accordance with Claim 91,  
wherein the step of administering said dosage level is for treating polymyositis-  
dermatomyositis.

95. A method for inhibiting the action of TNF in accordance with Claim 91,  
wherein the step of administering said TNF antagonist in the form of said thalidomide  
group is performed orally in said human wherein said dosage level is in the range of  
10mg to 300mg.

96. A method for inhibiting the action of TNF for treating neurological conditions  
in a human by administering a TNF antagonist for reducing the inflammation of neuronal  
tissue of said human, or for modulating the immune response affecting neuronal tissue of  
said human, comprising the step of:

- a) administering a therapeutically effective dosage level to said human  
of any TNF antagonist for reducing the inflammation of neuronal tissue of said human, or  
for modulating the immune response affecting neuronal tissue of said human; and
- b) administering said TNF antagonist into the cerebroventricular system.

97. A method for inhibiting the action of TNF in accordance with Claim 96, wherein the step of administering said TNF antagonist into the cerebroventricular system is by implanting in the scalp of said human a subcutaneous reservoir with a catheter attached for receiving said TNF antagonist, placing said catheter into the cerebroventricular system of said human, and accessing said reservoir by needle injection from the outside through the scalp of said human, thereby allowing the introduction of said TNF antagonists directly into said reservoir and said catheter to communicate and supply the TNF antagonists into the cerebrospinal fluid.

98. A method for inhibiting the action of TNF for treating conditions of the optic nerve or retina in a human by administering a TNF antagonist for reducing the inflammation of the optic nerve or retina of said human, or for modulating the immune response affecting the optic nerve or retina of said human, comprising the step of:

a) administering a therapeutically effective dosage level to said human of any TNF antagonist for reducing the inflammation of the optic nerve or retina of said human, or for modulating the immune response affecting the optic nerve or retina of said human; and

b) administering said TNF antagonist into the cerebroventricular system.

99. A method for inhibiting the action of TNF in accordance with Claim 98, wherein the step of administering said TNF antagonist into the cerebroventricular system is by implanting in the scalp of said human a subcutaneous reservoir with a catheter attached for receiving said TNF antagonist, placing said catheter into the  
5 cerebroventricular system of said human, and accessing said reservoir by needle injection from the outside through the scalp of said human, thereby allowing the introduction of said TNF antagonists directly into said reservoir and said catheter to communicate and supply the TNF antagonists into the cerebrospinal fluid.